

## REMARKS

With entry of this Amendment claims 37-40, 54, and 59-82 are pending in the application. Claims 1-36, 41-53, and 55-58 were previously cancelled without prejudice to their elective further prosecution in any related application(s). By this Amendment, claims 37, 54, 59, 66, 69, 73, and 76-78 have been amended for clarity and without prejudice to correct formalities or more distinctly recite certain aspects of the invention. All of the amendments herein are fully supported by the specification, and no new matter has been added to the application. Entry of this Amendment and consideration of the accompanying remarks is respectfully requested.

### **Election/Restrictions**

Applicants note for the record that no acquiescence is made with regard to the merits of the prior Restriction Requirement, and no representations are made by the resulting election with respect to the existence or non-existence of multiple, separate and distinct inventions in the original or current claims. Applicants note further that the issue of species election is rendered moot by the Office's withdrawal of the species election requirement (present Office Action/Mail Date 0922004, at page 2).

### **Patentability Under 35 USC § 112**

Claims 37-40, 54, and 59-82 are rejected under 35 USC § 112, first paragraph as allegedly failing to comply with the enablement requirement. In particular, the Office contends that the claims are not enabled on the basis that "there is no requirement in the claims that the MHC class II construct is specific for the antigenic determinant." Additional technical concerns regarding breadth and efficacy of the originally-presented claims are set forth at page 3 of the Office Action.

Applicants respectfully traverse the stated grounds for rejection and submit that the subject matter of the claims as currently amended fully satisfies the enablement requirements of 35 USC § 112, first paragraph.

The clarifying amendments to the claims presented above are believed to fully address and obviate the Office's stated grounds for rejection with regard to enablement. In this context, claim 37 has been amended recite that "the MHC Class II polypeptide is non-covalently associated or covalently conjugated with the antigenic determinant", and that "the MHC Class II

polypeptide associated or conjugated with the antigenic determinant reduces the immune response against the antigenic determinant in the subject". Claim 54 has been amended to recite that "the MHC Class II polypeptide is non-covalently associated or covalently conjugated with the antigenic determinant", that "an antigen-specific response by said T-cells directed against said antigenic determinant is a causal or contributing factor in said disease", "whereby said T-cells following exposure to said MHC Class II polypeptide and associated or conjugated antigenic determinant mediate or exhibit a reduction of antigen-specific T-cell pathogenic activity or potential in the patient."

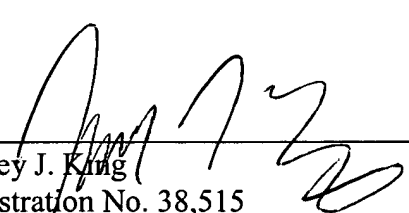
The specific subject matter presented in these amendments, particularly the antigen-specific activity for reducing an immune response or mediating treatment of disease mediated by the MHC II/antigen complexes and conjugates of the invention, is amply supported in Applicants' specification. Support for the foregoing amendments is found throughout the disclosure, for example at page 5, lines 7-14, page 6, line 22 to page 7, line 2, page 41, line 12 to page 42, line 16, and page 56, line 20 to page 57, line 16. Evidence regarding efficacy of the claimed subject matter, including *in vivo* efficacy, is likewise found throughout the disclosure, in particular as presented in the Examples.

### CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance, and thus an official action to that end is urged. If the Examiner believes that a telephone conference would aid in the prosecution of this case in any way, please call the undersigned at (425) 455-5575.

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